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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,086	03/26/2001	Dale Baskin	7414.0043	2844

22852 7590 06/15/2004

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
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WASHINGTON, DC 20005

EXAMINER	
TUNG, JOYCE	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,086	BASKIN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *51-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 2/11/2004 to the Office action has been entered. Claims 1-68 are pending. Claims 51-67 are withdrawn from further consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/2004 has been entered.

2. The rejection of claims 10, and 26-50 under 35 U.S.C. 112, second paragraph is withdrawn.

3. Claim 49 remains rejected under35 U.S.C. §112, second paragraph in section 4(e) since there is no specific argument regarding the rejection.

4. Claims 1-25 and 68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pritham et al. (J of Clinical Ligand Assay, 1998, Vol. (4), pg. 404-412) in view of Johnston-Dow et al. (6,103,465).

Pritham et al. disclose a rapid PCR method to monitor the amplification by detecting the fluorescent signal (See pg. 404, the abstract) involving using fluorescence probe (See pg. 405 column 2, second paragraph and pg 406 column 2 to pg. 409, column 1). The teachings of Pritham et al. are recited through out the limitations of claims 1-9, and 19-24, except that Pritham et al do not disclose the sequencing method used to detect a specific target nucleic acid as recited in the limitations of claim 1.

Pritham et al. also do not indicate the source of the DNA sample used as listed in claims 10, and 25 in the method.

Johnston-Dow et al. disclose a method for typing HLA class I gene and the method involving DNA sequencing techniques (See the Abstract and column 9, lines 9-22). The method is to provide for the specific DNA sequencing of HLA-A, HLA-B and HLA-C (See column 3, lines 19-22). Johnston-Dow et al. also disclose that any source of human nucleic acid can be used, for example, blood and lymphoblostoid cell lines (See column 6, lines 9-14) as recited in the limitations of claims 10, and 25. Johnston-Dow et al. further indicate that HLA typing is performed routinely in connection with many medical indications, the study of auto-immune disease and the determination of susceptibility to infectious disease (See column 1, lines 57-62). This teaching suggests the limitations of claims 11-18 in that the pathogen will be from a virus, prokaryote and eukaryote, the presence of the given target polynucleotide indicates the presence of the genetic disease or a specific allele which can indicate serotype.

It would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to combine the teachings of Pritham et al. and Johnston-Dow et al. to carry out the method as claimed with a reasonable expectation of success. The motivation is that the teachings of Pritham et al. indicate that fluorescent monitoring of PCR provides qualitative and quantitative information in that the qualitative information includes purity and identity (See pg. 404, column 1, last paragraph) and rapid cycle PCR is an ideal technique for fluorescence monitoring because temperature gradients within samples are minimized (See pg. 404, column 2, second paragraph) and the method of Johnson-Dow et al. is applied to the locus-specific nucleic acid amplification followed by sequence-specific detection of the amplified product for the DNA typing of HLA class I gene via DNA sequencing in that by sequencing the exons in both directions, the effect of sequencing errors on the assignment of HLA type is minimized and the method greatly reduces the number of reagents and the complexity of the sequencing protocols required (See column 9, lines 29-37).

The response argues that there is no motivation to combine and the motivation simply takes inventors hindsight from the disclosure. However, it takes into account only knowledge, which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from the applicant's disclosure. Thus, the motivation as set forth above is proper.

The response further argues that there is also no reasonable expectation of success in which the sequencing of amplification product was not predictable at the time when the invention was made, as shown by Sambrook et al. (Molecular Cloning: 3rd ed. 2001). However, Sambrook et al. indicates that the keys to success are rigorous optimization of the amplification step to suppress mispriming and meticulous purification to rid the PCR product of residual primer, thermostable DNA polymerase, unused dNTPs, and nonspecific reproductions of the original template. Based upon the teachings of Sambrook et al. there is way to obtain a reasonable expectation of success.

Based upon the analysis of the argument, the rejection is maintained.

5. Claims 26-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pritham et al. (J of Clinical Ligand Assay, 1998, Vol. (4), pg. 404-412) in view of Johnston-Dow et al. (6,103,465) as applied to claims 1-25 and 68 above, and further in view of Wittwer et al. (6,174,670).

The teachings of Pritham et al. and Johnston-Dow et al. are set forth in section 5 above. The teachings of Pritham et al. and Johnston-Dow et al. do not indicate that there are two reaction compositions involved in the methods.

Wittwer et al. disclose methods of monitoring hybridization during polymerase chain reaction using two pairs of oligonucleotides and a nucleic acid binding fluorescent dye to monitor amplification of a selected template (See column 13, lines 62 to column 14, lines 29).

Thus, it would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to combine the teachings of Pritham et al., Johnston-Dow et al. and Wittwer et al. to carry out the method as claimed with a reasonable expectation of success. The motivation of combining the teachings of Pritham et al. and Johnston-Dow et al. are discussed in section 5 above and the motivation of applying the teachings of Wittwer et al. is that the method of Wittwer et al. improves the sensitivity of PCR quantification and reduces the time of fluorescence monitoring for PCR.

The response argues that Wittwer et al. disclose a method that comprises a single reaction mixture and does not teach "at least one set of reaction compositions comprising a first reaction composition and second reaction composition...". However, since the claim language states "combining nucleic acid from the sample with at least one set of reaction composition comprising a first reaction composition and a second composition". the claim language is interpreted that the reaction can be a single reaction". Wittwer et al. disclose a single reaction with two sets of primer pairs (See column 13, lines 63-67 to column 14 lines 1-14). Therefore the teachings of Wittwer read on the limitations of claims. Thus the rejection is maintained

Summary

7 No claims are allowed.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

June 4, 2004

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
6/10/04